

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>In re Application of Jardieu et al. Serial No.: To be assigned Filed: September 19, 2003 For: METHOD OF TREATMENT USING HUMANIZED ANTI-CD11a ANTIBODIES</p>	<p><b>Express Mail No. EV 351932786 US</b> <b>Mailed September 19, 2003</b> CUSTOMER NO: 09157</p>
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

(If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.)

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in prior application Serial Nos. 08/974,899, filed November 20, 1997 and 09/795,798, filed February 28, 2001 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ (X) not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) (Required)
- ☐ in the form of an English language copy of a Search Report from a foreign patent office,

issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: September 19, 2003

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FORM PTO-1449  <b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)	U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P1014R1C1D1C1	Serial No.
		Applicant Jardieu et al.	
		Filing Date 19 Sep 2003	Group

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
* 1	4,816,567	28.03.89	Cabilly et al.			
* 2	5,622,700	22.04.97	Jardieu et al.			
* 3	6,037,454	14.03.00	Jardieu et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No	
* 4	364,690	25.04.90	EPO				
* 5	699,755	06.03.96	EPO				
* 6	EP 440,351	07.08.91	EPO				
* 7	WO 91/09967	11.07.91	PCT				
* 8	WO 91/16927	14.11.91	PCT				
* 9	WO 93/01296	21.01.93	PCT				
*10	WO 94/04188	03.03.94	PCT				
*11	WO 95/23813	08.09.95	PCT				
*12	WO 96/32478	17.10.96	PCT				
*13	WO 96/36359	21.11.96	PCT				
*14	WO 97/31024	28.08.97	PCT				

**OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)**

*15	Barry, J., "Immunosuppressive drugs in renal transplantation. A review of the regimens" <u>Drugs</u> 44:554-566 (1992)
*16	Brown, Jr. et al., "Anti-Tac-H, a humanized antibody to the interleukin 2 receptor, prolongs primate cardiac allograft survival" <u>Proc. Natl. Acad. Sci. USA</u> 88:2663-2667 (1991)
*17	Carter et al., "Engineering Subtilisin BPN' for Site-Specific Proteolysis" <u>Proteins: Struct. Funct., Genet.</u> 6:240-248 (1989)
*18	Carter et al., "Humanization of an Anti-pl85 <sup>HER2</sup> Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992)
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*20	Champe et al., "Monoclonal antibodies that block the activity of leukocyte function-associated antigen 1 recognize three discrete epitopes in the inserted domain of CD11a" <u>Journal of Biological Chemistry</u> 270:1388-1394 (1995)
*21	Chothia, C. et al., "Conformations of immunoglobulin hypervariable regions" <u>Nature</u> 342(6252):877-883 (1989)
*22	Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis" <u>Science</u> 244:1081-1085 (1989)
*23	Cunningham et al., "Receptor and Antibody Epitopes in Human Growth Hormone Identified by Homolog-Scanning Mutagenesis" <u>Science</u> 243:1330-1336 (1989)
*24	Dantal et al., "Use of Monoclonal Antibodies in Human Transplantation" <u>Current Opinion in Immunology</u> 3:740-747 (1991)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Filing Date 19 Sep 2003	Group
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
*25	de Fougerolles et al., "Characterization of ICAM-2 and evidence for a third counter-receptor for LFA-1" <u>Journal of Experimental Medicine</u> 174:253-267 (1991)				
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*37	Gorman et al., "High efficiency DNA-mediated transformation of primate cells" <u>Science</u> 221:551-553 (1983)				
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<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
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*47	Kelley et al., "Characterization of Humanized Anti-p185HER2 Antibody Fab Fragments Produced in Escherichia coli" <u>Protein Folding In Vivo and In Vitro</u> , Jeffrey L. Cleland, Washington, D.C.:American Chemical Society pps. 218-239 (1993)				
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*54	McCabe et al., "sICAM-1 Enhances Cytokine Production Stimulated by Alloantigen" <u>Cellular Immunology</u> 150:364-375 (1993)				
*55	McClure, H., "Nonhuman Primate Models for Human Disease" <u>Advances in Veterinary Science and Comparative Medicine</u> 28:267-304 (1984)				
*56	Nakakura et al., "Potent and Effective Prolongation by Anti-LFA-1 Monoclonal Antibody Monotherapy of Non-Primarily Vascularized Heart Allograft Survival in Mice Without T Cell Depletion" <u>Transplantation</u> 55(2):412-417 (February 1993)				
*57	Nishihara et al., "Potent immunosuppressive effect of anti-LFA-1 monoclonal antibody on islet allograft rejection" <u>Transplantation Proc.</u> 27:372 (1995)				
*58	Parlevliet et al., "Monoclonal antibodies in renal transplantation: a review" <u>Transplant Intl.</u> 5:234-246 (1992)				
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*61	Riechmann et al., "Reshaping Human Antibodies for Therapy" <u>Nature</u> 332:323-327 (Mar 24, 1988)				
*62	Saban et al., "Humanized Anti-IgE Monoclonal Antibody Mae25 Blocks Passive Sensitization of Rhesus Monkey Bladder In Vitro" <u>FASEB J.</u> (Abstract 3953) 8(5):A682 (March 18, 1994)				
*63	Simmons et al., "ICAM, an adhesion ligand of LFA-1, is homologous to the neural cell adhesion molecule NCAM" <u>Nature</u> 331:624-627 (1988)				
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